

DEPARTMENT OF THE NAVY

NAVAL SURFACE WARFARE CENTER

DAHLGREN DIVISION

DAHLGREN, VIRGINIA 22448-5000

IN REPLY REFER TO 8240.2

1019 '99 MeroG71/1003 21 Jun 99

From:

Commander, Dahlgren Division, Naval Surface Warfare Center

To:

US Food and Drug Administration

Dockets Management Branch (HFA-305)

5600 Fishers Lane Rockville, MD 20857

Subi:

PROPOSAL TO AMEND 21 CFR 1040.11 WITH A PARAGRAPH REGARDING

LASERS SOLD TO THE DEPARTMENT OF DEFENSE

Ref: (a) FDA Exemption #75EL01DOD

1. Reference (a) was issued to the Department of Defense (DoD) to allow the use of lasers used in combat, combat training, or classified in the interest of national security to deviate from 21 CFR laser safety requirements under some circumstances. This exemption has proven both necessary and useful.

- 2. Due to the proliferation of small and inexpensive laser devices, the DoD has seen a significant increase in the number of laser devices that manufacturers are selling directly to DoD groups and organizations. Many of these devices are advertised as being "FDA compliant" in order to bypass the DoD quality and safety assurance procedures for lasers exempted by reference (a). This back-door approach is allowing lasers that have parameters not verified by appropriate DoD branches to be used in conditions that may not be safe.
- 3. This issue was discussed at a recent DoD Laser System Safety Working Group (LSSWG) meeting. It was agreed at that meeting that the inclusion of a subsection in 21 CFR 1040.11 for lasers sold to the DoD would be appropriate and would close the loophole that allows potentially unsafe lasers into the DoD environment.
- 4. Please consider the inclusion of the following section to the new laser safety code:

¶ 1040.11 (d) Lasers Sold to DoD Activities
Lasers, regardless of class, manufactured for the DoD for the
pose of combat, combat training, or classified in the

rest of national security shall require approval of the v Under Secretary of Defense for Environmental Security.

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- Subj: PROPOSAL TO AMEND 21 CFR 1040.11 WITH A PARAGRAPH REGARDING LASERS SOLD TO THE DEPARTMENT OF DEFENSE
- 5. Any questions regarding this request should be forwarded to Mr. Robert Aldrich, Code G71, at (540) 653-1149.

Phono a. Del Suidi T. A. DELGUIDICE

By direction

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PROPOSAL TO AMEND 21 CFR 1040.11 WITH A PARAGRAPH REGARDING LASERS SOLD TO THE DEPARTMENT OF DEFENSE.			
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